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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,574	06/26/2003	Peter D. Gluckman	NRNZ-01005US1	4698

7590 09/17/2004

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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,574	GLUCKMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/719,459.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040322*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. The status of the U.S. parent application in the priority claim inserted at page 1 of the specification should be updated.

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 28-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,187,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '906 patent anticipate the instant claims. Because the same active agent is being administered to the same patients by the same method steps to treat the same disease states, inherently the amount of tyrosine hydroxylase within the central nervous system of the patients being treated will be increased; TH-mediated dopamine production by dopaminergic neurons within the substantia nigra of the CNS will be increased; and a decrease in TH-containing neurons and in TH within the CNS of the patients being treated will be inhibited; in the claimed invention of the '906 patent to the same extent as in the instant claimed invention. The mere determination of the physiological mechanism by which a prior art method operates does not impart patentability to claims drawn to the prior art method. With respect to instant claim 33, to the extent that the '906 patent claims protecting dopaminergic neurons against death

(see claims 1 and 4), the '906 patent is deemed to claim prophylactic treatment. With respect to instant claim 34, to the extent that the '906 patent claims administration subsequent to onset of Parkinson's disease (see claim 2), the '906 patent is deemed to claim therapeutic treatment.

4. Claims 28-46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 09/866,536. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '536 application anticipate the instant claims. Because the same active agents are being administered to the same patients by the same method steps to treat the same disease states, inherently the amount of tyrosine hydroxylase within the central nervous system of the patients being treated will be increased; TH-mediated dopamine production by dopaminergic neurons within the substantia nigra of the CNS will be increased; and a decrease in TH-containing neurons and in TH within the CNS of the patients being treated will be inhibited; in the claimed invention of the '536 application to the same extent in the instant claimed invention. The mere determination of the physiological mechanism by which a prior art method operates does not impart patentability to claims drawn to the prior art method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 28-32 and 34-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,682,753. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '753 patent anticipate the instant claims. Note that the '753 patent

claims the treatment of mammals with Parkinson's disease (see claim 13). Because the same active agent is being administered to the same patients by the same method steps to treat the same disease states, inherently the amount of tyrosine hydroxylase within the central nervous system of the patients being treated will be increased; TH-mediated dopamine production by dopaminergic neurons within the substantia nigra of the CNS will be increased; and a decrease in TH-containing neurons and in TH within the CNS of the patients being treated will be inhibited; in the claimed invention of the '753 patent to the same extent as in the instant claimed invention. The mere determination of the physiological mechanism by which a prior art method operates does not impart patentability to claims drawn to the prior art method.

6. Claims 41-44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,780,848. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '848 patent anticipate the instant claims. Because the same active agent is being administered to the same patients by the same method steps to treat the same disease states, inherently a decrease in TH-containing neurons and in TH within the CNS of the patients being treated will be inhibited in the claimed invention of the '848 patent to the same extent as in the instant claimed invention. Sufficient evidence of similarity is deemed to be present between the claimed invention of the '848 patent and the instant claimed invention to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than that of the claimed invention of the '848 patent. The mere determination of the physiological mechanism by which a prior art method operates does not impart patentability to claims drawn to the prior art method.

7. Instant claims 28-46 are deemed to be entitled under 35 U.S.C. 119(a)-(d) to the benefit of the filing date of the foreign priority document because the foreign priority document, under the test of 35 U.S.C. 112, first paragraph, discloses the instant claimed invention.

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Gluckman et al (U.S. Patent No. 6,780,848). Gluckman et al teach administering GPE to a mammal before or after injury to the CNS of the mammal. See, e.g., the Abstract. Because the same active agent is being administered to the same patients by the same method steps to treat the same disease states, inherently a decrease in TH-containing neurons and in TH within the CNS of the patients being treated will be inhibited in Gluckman et al to the same extent as in the instant claimed invention. Sufficient evidence of similarity is deemed to be present between Gluckman et al and the instant claimed invention to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than that of Gluckman et al. The mere determination of the physiological mechanism by which a prior art method operates does not impart patentability to claims drawn to the prior art method.

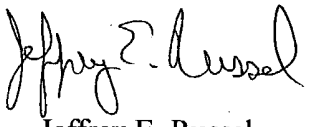
10. Gluckman et al (U.S. Patent No. 6,780,848) is equivalent to the parent application of U.S. Patent No. 6,187,906, applied in the above obviousness-type double patenting rejection, and to the parent application of Gluckman et al (U.S. Patent Application Publication 2002/0035066).

To the extent that U.S. Patent No. 6,187,906 and/or Gluckman et al (U.S. Patent Application Publication 2002/0035066) might be prior art against the instant claims, they are duplicative of Gluckman et al (U.S. Patent No. 6,780,848). Gluckman et al (U.S. Patent No. 6,780,848) contains only a single mention of the treatment of Parkinson's disease, does not contain any examples directed to the treatment of Parkinson's disease, and does not contain any disclosure of dopaminergic neurons or of the possibility that its active agents have any effect on dopaminergic neurons, and therefore is not deemed to anticipate or suggest instant claims 28-40, 45, and 46.

U.S. Patent No. 6,617,311 is cited as art of interest, but is not deemed to raise any issues of obviousness-type double patenting with the instant claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1654

JRussel
September 16, 2004